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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc., Plaintiffs, v. Deva Holding A.S. (a/k/a Deva Holdings A.S.) Defendant.	C.A. No.: 2:24-cv-04404-SRC-MAH

DEVA HOLDING A.S.'S REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT PURSUANT TO FED. R. CIV. P 12(b)(1)

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I. INTRODUCTION

Plaintiffs' opposition brief (D.I. 16) failed to address either of the two grounds Defendant Deva relies on for its motion (D.I. 11). First, Plaintiffs failed to point out any allegations in the Complaint that could establish *immediacy* to satisfy the "case or controversy" Constitutional requirement. Plaintiffs pointed to nothing indicating that the FDA is about to approve Deva's ANDA and allow an imminent product launch by Deva, or that Deva is "preparing to manufacture its product." Because of Plaintiffs' silence, the Declaratory Judgment Act counts (all even-numbered counts in the Complaint) must fail, and be dismissed.

Plaintiffs also failed to address Deva's actual argument regarding the Hatch-Waxman Act counts (all odd-numbered counts). Deva explained that any asserted patent brought under 35 U.S.C. § 271(e)(2)(A) is required to claim "a drug" or the use of a drug. (D.I. 11-1, at 6 ("None of the Asserted Patents Claim a 'Drug'")). Plaintiffs do not dispute that the asserted Fenlon and Walsh patents claim only mechanical structures, and not any drug. Plaintiffs do not dispute that the Court's ruling in *Teva v. Amneal* that the Fenlon and four of the Walsh patents *do not claim* any drug can inform the interpretation of patent claim coverage for the instant case. Because it is undisputed that the asserted patents here do not claim a drug, the consequence flowing from the plain text of § 271(e)(2)(A) is clear—the statute does not confer any jurisdiction based on non-drug patents, for example these "mechanical structure" patents Plaintiffs are now asserting against Deva. Plaintiffs' briefing is silent on what the text of 35 U.S.C. § 271(e)(2)(A) actually requires. For these reasons, the entire Complaint must be dismissed.

II. ARGUMENT

A. All Declaratory Judgment Counts Must Be Dismissed Because Plaintiffs Cannot Point to Any Allegations That Would Support "Immediacy"

Deva pointed out in its opening brief that Plaintiffs made no allegations supporting "immediacy" despite having the burden to do so. (D.I. 11-1, at 4-5). In response, Plaintiffs admitted that the law requires factual allegations to show "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." (D.I. 16, at 8 (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007))). Plaintiffs cited case law for the proposition that a case or controversy exists when an ANDA filer is "systematically attempting to meet the applicable regulatory requirements while preparing to manufacture its product." (*Id.* at 9 (citing *Cephalon, Inc. v. Sandoz, Inc.*, No. 11-821, 2012 WL 682045, at *5 (D. Del. Mar. 1, 2012) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997))). Yet, Plaintiffs' Complaint failed to clear the jurisdictional hurdle even under their own recitation of case law.

The Federal Circuit opinion in *Glaxo v. Novopharm* included an important notation that the ANDA filer Novopharm had "indicated that it had submitted an ANDA accompanied by data sufficient *to make FDA approval imminent*." *Glaxo*, 110 F. 3d at 1571 (emphasis added). At least partly based on this fact, the Federal Circuit concluded that "the threat of Novopharm entering the U.S. market was not 'years away.'" *Id.* Furthermore, the Federal Circuit explained that "declaratory relief is available to the patentee asserting a 'method of making' claim if, as here, *sufficient facts are alleged* to created an actual case or controversy. Such allegations may include, as here, *imminent* FDA approval and *actual threats* of future infringement." *Id.* (Emphases added). Instead of meeting this requirement of pleading sufficient facts, Plaintiffs' Complaint is

altogether missing any allegations of "imminent FDA approval" or "actual threats of future infringement."[1]

Plaintiffs had the opportunity to explain where in their Complaint they pled indications of an "imminent approval" of Deva's ANDA, or that Deva is "preparing to manufacture its product." Plaintiffs failed to do so. On this issue, Plaintiffs cited only four paragraphs of the Complaint in their opposition brief. (D.I. 16, at 9). Among these, paragraphs 6 and 63 merely allege that Deva filed an ANDA containing a Paragraph IV Certification and sent Teva a notice letter. (D.I. 1, at ¶¶ 6, 63). Paragraph 64, in its entirety, alleges that "[t]he purpose of Deva's submission of Deva's ANDA to FDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the Patents-in-Suit." (*Id.* at ¶ 64). Paragraph 7 alleges that, "following any FDA approval of Deva's ANDA, Deva will commercially manufacture, [etc.] the Deva ANDA Product in and/or into the United States, including New Jersey." (*Id.* at ¶ 7). There is no allegation of any imminent approval of Deva's ANDA. In fact, Plaintiffs' use of the term "any FDA approval" indicates uncertainties on *whether* the ANDA will be approved at all, at any time.

[1] Deva does not suggest that the mere recitation of "imminent FDA approval," "actual threats," or "active preparation for manufacturing" would have been sufficient for Plaintiffs to meet the requirement of showing "immediacy" for declaratory judgment jurisdiction to attach. *See Teva Pharmaceuticals Int'l GmbH v. Eli Lilly & Co.*, C.A. No. 1:17-cv-12087-ADB, 2018 WL 10246999, at *6-*7, *9 (D. Mass. Sept. 27. 2018) (despite the plaintiffs' allegations of "imminent FDA approval and actual threats of future infringement," the district court dismissed the case for a lack of subject matter jurisdiction because of (a) uncertainties in the timing of FDA approval of the biologic drug application at issue and (b) the defendant's silence on whether FDA approval of their applied-for drug would be "imminent").

Plaintiffs in the instant case made even *fewer* allegations to suggest any "immediacy" than those in *Teva v. Eli Lilly*. Here, Plaintiffs did not even make any allegations of "imminent [Deva] drug application approval and actual threats of future infringement."

Therefore, Plaintiffs appear to treat Deva's filing of a Paragraph IV certification-containing ANDA, by itself, as showing an "imminent" approval which would allow immediate actual infringing activities. Plaintiffs never alleged that the ANDA approval is sufficiently likely to occur, and imminent, to generate any "actual threats of future infringement." The allegations are barebones, did not go beyond the mere filing of an ANDA, and are silent as to the approval likelihood and timing of Deva's ANDA.

The mere filing of a Paragraph IV certification-containing ANDA is not sufficient to create a case or controversy. In its opening brief, D.I. 11-1, at 5, Deva quoted the Supreme Court's opinion in *Eli Lilly & Co. v. Medtronic, Inc.* that 35 U.S.C. § 271(e)(2) created "a new (and somewhat artificial) act of infringement." 496 U.S. 661, 676 (1990). By referring to an ANDA filing as a "new and artificial" act of infringement, the Supreme Court acknowledged that such a filing, without more, would not ordinarily have triggered Declaratory Judgment Act jurisdiction, and that is why the jurisdiction-conferring provision § 271(e)(2) was enacted to define a "new" act of infringement. Plaintiffs offered no counter-argument on this point.

To summarize, the controlling Supreme Court and Federal Circuit case law requires more than the mere recitation of an ANDA filing to establish jurisdiction under 28 U.S.C. § 2201(a). A new statute (35 U.S.C. § 271(e)(2)(A)) was required to define a "new" type of infringement to provide jurisdiction for federal courts to hear cases based on ANDA filings. For an ANDA filer to be properly sued under 28 U.S.C. § 2201(a), a plaintiff must allege "sufficient facts" (i.e. more than the mere filing of an ANDA), such as "imminent FDA approval and actual threats of future infringement" (i.e. more than a potential and future FDA approval, plus any possible future infringement upon FDA approval of the ANDA, if such approval materializes at some point, maybe years away). *Glaxo v. Novopharm*, 110 F. 3d at 1571.

Plaintiffs also stated that "courts routinely allow declaratory judgment claims to proceed after the filing of an ANDA but before approval." (D.I. 16, at 9-10) (citing *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344 (Fed. Cir. 2004), *Glaxo v. Novopharm* (discussed above), and *Cephalon* (unreported District of Delaware opinion)). In *Glaxo v. Apotex*, the Federal Circuit noted that the complaint alleged both "anticipatory infringement" and "artificial infringement pursuant to 35 U.S.C. § 271(e)(2)(A)," then proceeded to discuss the jurisdiction-conferring function of the Hatch-Waxman Act provision, followed by an analysis of the merits of the case. *Glaxo v. Apotex*, 376 F.3d at 1344. There is no indication in the opinion that the Federal Circuit considered declaratory judgment counts in a Hatch-Waxman Act case "routine." There was no discussion on whether the filing of an ANDA, by itself, would provide the "immediacy" to trigger declaratory judgment jurisdiction under 28 U.S.C. § 2201(a).

In *Cephalon*, the district court relied on *Glaxo v. Novopharm* to reject "the administrative paradigm of the Hatch-Waxman Act to preclude a patent holder from establishing jurisdiction under 28 U.S.C. § 2201(a)." *Cephalon*, 2012 WL 682045, at *5. The *Cephalon* court eventually found jurisdiction "pursuant to 35 U.S.C. § 271(e)(2) and/or 28 U.S.C. § 1338(a)." *Id.* at *6. However, it is unclear from the opinion what allegations of facts the district court relied on to satisfy itself that there was "a sufficient allegation of immediacy and reality." *Id.* (citing *Glaxo v. Novopharm*, 110 F.3d at 1570). As discussed above, the Federal Circuit has articulated a requirement in *Glaxo v. Novopharm* for allegations of "sufficient facts" such as "imminent FDA approval and actual threats of future infringement" to create a case or controversy. Mere recitation of ANDA filing and Paragraph IV certification is not sufficient.

B. All Hatch-Waxman Act Counts Must Also Be Dismissed Because None of the Asserted Patents Claim a "Drug"

The plain text of 35 U.S.C. § 271(e)(2)(A) requires "a drug claimed in a patent," or that "the use of [a drug] is claimed in a patent." The Federal Circuit has also made it clear that *only* patents that claim a drug or a method of using a drug can trigger § 271(e)(2)(A) jurisdiction. *Glaxo v. Novopharm*, 110 F.3d at 1570 (the statute "provides the federal courts with jurisdiction to hear infringement cases regarding claims directed to drugs or to methods of using drugs, it does not provide jurisdiction to hear infringement cases regarding claims directed to methods for making drugs."). According to both the plain text and the Federal Circuit interpretation of the § 271(e)(2)(A) statute, whether an asserted patent has "claims directed to drugs or methods of using drugs" is a necessary and dispositive question in a jurisdictional inquiry. *Id.*

This § 271(e)(2)(A) jurisdictional question is focused only on the asserted patents themselves, and does not involve any analysis of the accused product. On the other hand, whether the accused product infringes any asserted claim is a question on the merits, but it is a different and separate question from the jurisdictional one. In this case, it so happens that the claim interpretation relevant to the jurisdictional inquiry has already been started and largely completed by this Court in *Teva v. Amneal*. (D.I. 11-1, at 6-8). The Court held in the *Amneal* case that "patents that claim a drug product" mean "those patents that claim the drug product that is described in the pending or approved NDA," which is an albuterol sulfate finished dosage form described in Teva's NDA. *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of NY, LLC*, __ F. Supp. 3d __, 2024 WL 2923018, at *8 (D.N.J. June 10, 2024). The asserted patents in the *Amneal* case, and in this case, do not have such a claim scope. (D.I. 11-1, at 7-8).

Plaintiffs never addressed the relevant jurisdictional question, which is, "do any of the asserted patents in this case claim a drug?" Instead, Plaintiffs first tried to suggest that any

allegation of patent infringement under § 271(e)(2) is sufficient to create jurisdiction. (D.I. 16, at 4). That is not the law. The case law cited by Plaintiffs all involved asserted patents that indeed claim a drug or the use thereof. Therefore, § 271(e)(2)(A) jurisdiction was proper in all those cases for the same reason that jurisdiction is *lacking* in the instant case; it all depends on what the answer to the relevant jurisdictional question is.

AstraZeneca Pharms. LP v. Apotex Corp., which Plaintiffs cited for support, involved two method-of-use patents for rosuvastatin calcium. 669 F.3d 1370, 1376 (Fed. Cir. 2012). The Federal Circuit expressly noted that "the plaintiff held method patents directed toward certain uses of a drug, … and the plaintiff brought suit claiming that the ANDAs infringed its method of use patents under § 271(e)(2)." *Id.* at 1377. Therefore, the assertion of these method-of-use patents properly invoked § 271(e)(2)(A) jurisdiction.

Plaintiffs also relied heavily on *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117 (Fed. Cir. 2018). (D.I. 16, at 4-5). *Vanda* involved the '610 patent, which claimed "a method of treating a patient with iloperidone," a drug. *Vanda*, 887 F.3d at 1121. The defendants in the *Vanda* case never contended that the '610 patent did not claim a drug or a method of using a drug. Accordingly, once the plaintiff asserted the '610 patent under 35 U.S.C. § 271(e)(2), there was jurisdiction. *Id.* at 1124.

Plaintiffs also cited *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012). (D.I. 16, at 5). In *Caraco*, Novo Nordisk asserted "a patent for one of the three FDA-approved uses of repaglinide." 566 U.S. at 409. Again, there was no dispute that the asserted patent satisfied the § 271(e)(2)(A) jurisdictional requirement—because it claims "the use of a drug."

It is indeed rare that a plaintiff would try to invoke 35 U.S.C. § 271(e)(2) jurisdiction when none of the asserted patents claim a drug or a method of using a drug, any drug. That rare situation is the case here. None of the case law Plaintiffs relied on addresses such a situation.

Proving infringement (i.e. matching patent claims to the *accused ANDA product*) "is a merits question, not a jurisdictional one." *Caraco*, 566 U.S. at 412 n.5; *Vanda*, 887 F.3d at 1125. Plaintiffs went against this clearly established law, and tried to portray the jurisdictional inquiry in this case as determining "the want of an infringing act," and urged the Court to consider this "merits problem" in the later stage of this case. (D.I. 16, at 5). In contrast, Deva's argument is consistent with this point of law—that the jurisdictional question and the merits question are different and separate. Plaintiffs must first show that the patents they assert actually cover a drug, any drug, rather than a mechanical device untethered to albuterol sulfate, before this lawsuit can proceed under 35 U.S.C. § 271(e)(2) for a separate determination of infringement or noninfringement by Deva's ANDA product. (D.I. 11-1, at 6). As Deva pointed out, "after a proper patent that claims 'a drug' is asserted, whether the accused ANDA product would match with, and therefore infringe, such a patent is a question of merits." (*Id.*). Plaintiffs tried to sidestep Deva's argument by wrongly characterizing the jurisdictional question as one on the merits. (D.I. 16, at 5 ("Deva's argument that the Asserted Patents do not claim a 'drug' is an argument on the merits, which is not properly raised in a jurisdictional challenge.")). In doing so, Plaintiffs never disputed Deva's central contention that *none of the asserted patents claim a drug*. Plaintiffs' silence on this point is dispositive to this motion.

Plaintiffs also made a number of arguments regarding Orange Book listing or delisting of the asserted patents, but none of those arguments are relevant to the jurisdictional question in this case. (D.I. 16, at 6-7). Deva's motion is based on the plain text of 35 U.S.C. § 271(e)(2)(A),

which limits the application of the artificial infringement to "a drug [or the use of which] claimed in a patent." This text does not require any listing of patents in the Orange Book. The rarely needed jurisdictional inquiry relevant to this case is simply whether any of the asserted patents claim a drug or a method of using a drug—and in this case, the answer is "no." The Court has arrived at the same conclusion, albeit in a different context, in the *Teva v. Amneal* case. (D.I. 11-1, at 6).

III. CONCLUSION

For the reasons stated above and in Defendant Deva's opening brief (D.I. 11-1), and for any other reason the Court deems just and proper, Deva respectfully requests that the Court grant its motion (D.I. 11) and dismiss with prejudice the Complaint in its entirety.

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